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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/735,602	12/12/2003	Hao-Jan Lin	JCLA10516	1741
23900	7590	05/31/2006	EXAMINER	
J C PATENTS, INC. 4 VENTURE, SUITE 250 IRVINE, CA 92618			GUIDRY, GUY L	
			ART UNIT	PAPER NUMBER
			1636	

DATE MAILED: 05/31/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/735,602	LIN ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Guy Guidry, Ph.D.	1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 20 March 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-15 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-15 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 12 December 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

**DETAILED ACTION**

Receipt is acknowledged of a response filed 20 March 2006 to the Office Action mailed 11 January 2006. Claims 1-15 are currently pending and under consideration in this Action. All previous objections/rejections not repeated herein are hereby withdrawn. A response to Applicant's arguments will be set forth, where appropriate, immediately following any statement of rejection repeated herein.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

**Claims 1-15 were rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.**

***Response to Applicant's amendments and arguments***

Applicant's amendments to claims 1 and 11 to more clearly include a valve as part of the controller and wording in claims 8 and 13 that the outlet is the sprayer's outlet overcome the previous rejection due to indefiniteness of these claims. Rejection to claims 1-15 under 35 U.S.C. 112 is therefore **withdrawn**.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

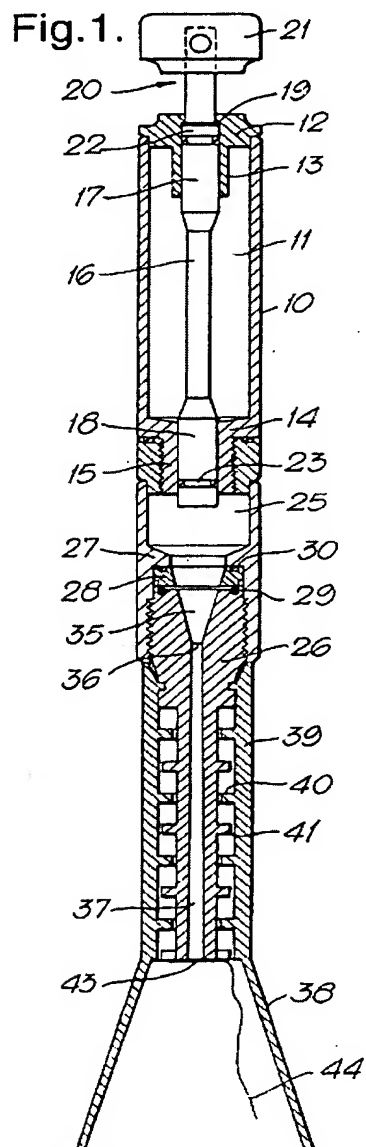
**Claims 1-8, 10-13 and 15 rejected under 35 U.S.C. 102(b) as being anticipated by Bellhouse et al., 1994, WO 94/24263 (hereinafter Bellhouse).**

This is a new ground of rejection.

Bellhouse teaches a needle-less syringe using supersonic gas flow for particle delivery comprising a gas chamber, the gas of which is discharged by way of an actuating pin (meeting the limitation to the controller valve of the instant inventions wherein a valve is understood by a person of skill in the art to mean a device that controls the movement of liquids or gases through pipes or other passages by opening or closing ports and channels) into a rupture chamber (equivalent to the instant claims pressurized chamber) until the gas establishes pressure wherein the chamber contains a membrane comprising at least the biological material to be delivered (meeting the limitation of triggering the gun and providing gas through the controller valve to the pressurized chamber until the gas establishes pressure). The sample solution comprising at least the biological material is released from the material delivery system when the membrane ruptures and is accelerated by the gas in the pressurized chamber. The sprayer, illustrated in Figures 1 of Bellhouse includes a converging/diverging

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spray nozzle (the lower hatched area between the segments labeled 35 and 37) and diverging straight discharge tube (the bottom element of the sprayer labeled 38). The device of Bellhouse therefore contains all of the structural elements of the gene gun device of claims 1, 11 and dependent claims.



Bellhouse teaches that the material to be delivered may be biological including genetic material, p. 2, ¶12, meeting the limitation of nucleic acid (claim

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2), insulin and calcitonin, (protein of claim 3), viruses or protein for immunization (claims 4-6) p. 3, ll. 20-24 or material for genetic therapy, p. 2, l. 9 (claim 15).

Particle velocity may be between 200-2,500m/sec, p. 4, l. 30 (claim 7). The gas employed in using the device may be helium, p. 7, l. 13 (claim 10). The angle between the diverging part and the center axis of the Bellhouse spray tube is also less than 15 degrees, see Fig. 1 above between the sections marked 36 and 43 (claims 9 and 14). Further, the interior contour of the converging part of the spray neck at the section labeled 36 appears to meet the limitation of claims 9 and 14 defined by the range  $rt < Rt < 2rt$  where  $Rt$  is the curvature radius of the converging part and  $rt$  the radius of the spray neck. Also, as the reference device is similar in design to the instant claimed inventions, presumably a pressure at the sprayers outlet of about 1 atmosphere may be achieved (claim 8). The Office does not have the facilities for examining and comparing Applicant's product with the product of the prior art in order to establish that the product of the prior art does not possess the same material, structural and functional characteristics of the claimed product. In the absence of evidence to the contrary, the burden is upon the applicant to prove that the claimed products are functionally different than those taught by the prior art and to establish patentable differences. See *Ex parte Phillips*, 28 USPQ 1302, 1303 (BPAI 1993), *In re Best*, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and *Ex parte Gray*, 10 USPQ2d 1922, 1923 (BPAI 1989).

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***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

**Claims 1-2 and 4-15 were rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-6, 9-10 and 12-22 of U.S. Patent No. 6, 436,709.**

***Response to Applicant's amendments and arguments***

Applicant has filed a Terminal Disclaimer to obviate the rejection over claims of U.S. Patent No. 6,436,709. Therefore, the rejection of instant claims based on the judicially created doctrine of nonstatutory double patenting is hereby **withdrawn**.

### ***Conclusion***

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Guy Guidry, Ph.D. whose telephone number is 571-272-7928. The examiner can normally be reached on Monday through Friday 9:00-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel, Ph.D. can be reached on 571-272-0781. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) (<http://pair-direct.uspto.gov>) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to



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answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

Guy Guidry, Ph.D.

Examiner

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**DANIEL M. SULLIVAN**  
**PATENT EXAMINER**